510(k): K093316

MAR 13 2009

5. 510(k) Summary as required by 21 CFR 807.92(c)

510(k) Owner: Topcon Corporation.
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174

U.S. Facility:
Topcon Medical Systems, Inc.
37 West Century Road
Paramus, New Jersey 07652
Telephone: (201) 599-5153
Facsimile: (201) 599-5240

Contact person: Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
310 Terrace Avenue
Suite 201
Cincinnati, OH 45220
Phone: (513) 961-8200
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Date: October 12, 2008

Trade Name: 3D OCT-1000 MARK II

Common names: Optical Coherence Tomography System
OCT
Mark II

Classification Name: Tomography, Optical Coherence
21 CFR§886.1570 Ophthalmoscope

Product Code: OBO (Tomography, Optical Coherence)

Identification of a Legally Marketed Predicate Device
The 3D OCT-1000 MARK II is substantially equivalent to the 3D OCT-1000 Optical Coherence Tomography System marketed by Topcon, 510(k) Premarket Notification Number K063388, FDA Product Code OBO.

General Description

510 (k): K083116

The Topcon 3D OCT-1000 is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema and central serous retinopathy.

The 3D OCT-1000 Mark II has the same intended uses and indications for use as the 3D OCT-1000. The technological characteristics are the identical for the two devices, with the exception that during OCT imaging, the scan pattern for the 3D OCT-1000 is delivered as continuous wave (CW) light source; whereas, it is delivered as pulsed lighting in the 3D OCT-1000 Mark II.

Intended Use
The Topcon 3D OCT-1000 MARK II is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema and central serous retinopathy.

Performance Data
Software validation testing and image capture testing were performed on the 3D OCT-1000 MARK II. Test results for the 3D OCT-1000 MARK II demonstrated sufficient agreement with captured images from the 3D OCT-1000. The results of performance testing and software validation testing did not raise any issues on the safety or effectiveness of the device.

Basis of Substantial Equivalence
The 3D OCT-1000 MARK II is substantially equivalent to the 3D OCT-1000 Optical Coherence Tomography System marketed by Topcon, 510(k) Premarket Notification Number K-63388, FDA Product Code OBO, and regulation 21CFR§886.1570 (Ophthalmoscope) in technological characteristics, engineering design and specifications, software design and specifications, laser classification and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2009

Topcon Medical Systems, Inc
c/o Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
310 Terrace Avenue, Suite 201
Cincinnati, OH 45220

Re: K083316
Trade Name: 3D OCT-1000 Optical Coherence Tomography System
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: October 12, 2008
Received: November 12, 2008

Dear Dr. Fant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K063316

Device Name: 3D OCT-1000 MARK II

Indications for Use:

The Topcon 3D OCT-1000 MARK II is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema and central serous retinopathy.

Prescription Use __X_____ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K063316